

REMARKS

The present communication responds to the Office Action dated November 16, 2006 and the Advisory Action dated March 8, 2007. In that Advisory Action, the Examiner maintained the rejection of Claims 29-37 under 35 U.S.C. § 103(a). In view of the following remarks, Applicant requests entry, reconsideration, and allowance of the pending claims.

Rejections Under 35 U.S.C. § 103

Claims 29 and 34 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Lee (U.S. Patent 5,292,332) in view of Clark (U.S. Patent 5,259,835). Applicant respectfully traverses the rejection for at least the following reasons.

Claim 29, as currently amended, is directed to a lumen occlusion device. The lumen occlusion device comprises, in part, “a plug defining a plurality of openings, the plug being configured and dimensioned to occlude flow through the lumen” and further comprises, in part, “a biological bonding agent for being moved through the openings; wherein the plurality of openings are generally arranged to allow the biological bonding agent to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to the interior of the lumen.” Claim 34, as currently amended, is directed to a method of occluding a body lumen. The method comprises, in part, “providing a device comprising a plugging means adapted for occluding flow through the body lumen . . . , wherein the plugging means has a plurality of openings generally arranged to allow a biphasic material to extrude through the plurality of openings to the interior wall of the lumen for binding the plugging means to the interior of the lumen.”

Neither Lee nor Clark, alone or in combination, disclose, teach, or suggest Applicant's invention.

As the Examiner points out, Lee fails to disclose, teach, or suggest a plug having a plurality of openings or a biological bonding agent for being moved through the openings. Lee further fails to disclose, teach, or suggest a plug “configured and dimensioned to occlude flow through the lumen.” Rather, Lee discloses a method and device for closing a puncture in an artery wall. *Lee, Abstract*. In one embodiment, Lee discloses a screw-plug for threading into a

puncture site of an arterial wall, which resulted from an arterial sheath used during an intravascular procedure. *Lee, Col. 3, ll. 40-Col. 5, ll. 66.* In a further embodiment, Lee discloses a plug member that may be disposed on the outside arterial wall to close a puncture site, which resulted from an arterial sheath used during an intravascular procedure. *Lee, Col. 5, ll. 67-Col. 7, ll. 18.* In either embodiment, the plug becomes part of the arterial wall. Lee nowhere discloses that flow through the artery is occluded. Furthermore, contrary to the Examiner's assertion in the present office action, Lee teaches away from occluding flow through the artery since the stated objective in Lee is obtained by providing a method for closing a puncture in a wall of an artery to seal the artery wall. *Lee, Col. 2, ll. 11-13.* Lee, in fact, explains that the disclosure is directed toward a medical device for percutaneously sealing a puncture in an artery without impeding blood flow within the lumen. *Lee, Col. 1, ll. 8-12.*

In the Advisory Action, the Examiner asserts that Lee teaches "a closure for a lumen that structurally impedes the lumen while still allowing some flow – as the present invention allows flow of the biological bonding agent," and similarly asserts that the plug of Lee "occludes flow – albeit still allows some flow of material as does the present invention." Applicant respectfully asserts that the Examiner has materially misunderstood the present invention.

First, the present invention provides a lumen occlusion device and a method for occluding a lumen. The Oxford English Dictionary defines the verb occlude as "[t]o block or stop up so as to prevent anything from passing in, out, or through; to obstruct; to close (an opening, esp. an orifice or pore)." Similarly, the Merriam-Webster Dictionary defines the verb occlude as "to close up or block off." From the disclosure in Lee, it is clear that the device disclosed in Lee is not a lumen occlusion device. As the Examiner has asserted, Lee allows flow through the lumen. Lee is a plug for closing a puncture site of an arterial wall. The plug in Lee is meant to mend a lumen, so that flow through the lumen can occur without leakage.

Second, the Examiner asserts that the present invention allows flow through the occlusion device. As the Examiner should recognize, the definitions for the verb occlude provided above instill a characteristic whereby flow through the lumen is blocked. Furthermore, the claims as amended recite that the plurality of openings are generally arranged to allow a biological bonding agent or biphasic material to extrude through the plurality of openings to the interior

wall of the lumen. Therefore, Lee does not disclose, teach, or suggest a lumen occlusion device comprising “a plug defining a plurality of openings, the plug being configured and dimensioned to occlude flow through the lumen” and further comprises, in part, “a biological bonding agent for being moved through the openings; wherein the plurality of openings are generally arranged to allow the biological bonding agent to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to the interior of the lumen.” Lee further does not disclose, teach, or suggest “providing a device comprising a plugging means adapted for occluding flow through the body lumen . . . , wherein the plugging means has a plurality of openings generally arranged to allow a biphasic material to extrude through the plurality of openings to the interior wall of the lumen for binding the plugging means to the interior of the lumen.”

Clark fails to remedy the fundamental deficiencies of Lee as a reference. Clark discloses an external wound closure device employing a porous bonding member which receives a flowable adhesive for adhering the bonding member to the skin of the patient. *Clark, Abstract*. Particularly, Clark discloses a device for apposing the edges of an external wound. *Id.* Clark does not disclose subject matter having any relation to lumen occlusion. As such, Clark does not disclose, teach, or suggest a lumen occlusion device nor method of lumen occlusion. Clark merely discloses a particular embodiment of adhesive bandages for closing external skin wounds. The mere fact that Clark discloses a flowable adhesive does not provide the incentive to combine Clark under § 103 with any other reference.

Thus, for at least the preceding reasons, neither Lee nor Clark, alone or in combination, disclose, teach, or suggest the inventions of Claim 29 and 34. Accordingly, reconsideration and withdrawal of the rejection is requested.

Claims 30-33 and 35-37 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Lee and Clark, as applied to Claims 29 and 34 above, and further in view of Wallace (U.S. Patent 6,585,754). Applicant respectfully traverses the rejection for at least the following reasons.

As discussed above, neither Claim 29, from which Claims 30-33 depend, or Claim 34, from which Claims 35-37 depend, are made obvious by the asserted Lee/Clark combination.

Wallace fails to remedy the fundamental deficiencies of the Lee/Clark combination. Wallace discloses compositions comprising absorbable implantable vaso-occlusive members. *Wallace, Abstract.* Wallace discloses an indirect method of lumen occlusion, i.e., embolization. Wallace does not disclose, teach, or suggest a lumen occlusion device comprising “a plug defining a plurality of openings, the plug being configured and dimensioned to occlude flow through the lumen” and further comprises, in part, “a biological bonding agent for being moved through the openings; wherein the plurality of openings are generally arranged to allow the biological bonding agent to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to the interior of the lumen,” as recited in claim 29. Wallace further does not disclose, teach, or suggest a method of occluding a body lumen comprising “providing a device comprising a plugging means adapted for occluding flow through the body lumen . . . , wherein the plugging means has a plurality of openings generally arranged to allow a biphasic material to extrude through the plurality of openings to the interior wall of the lumen for binding the plugging means to the interior of the lumen,” as recited in claim 34.

Furthermore, there is no teaching, suggestion, or motivation to make the combination asserted by the Examiner. The mere fact that the implantable vaso-occlusive member in Wallace is made of absorbable material does not provide the incentive to combine with another reference solely to add absorbable material to the list of compositions in the other reference.

For at least these reasons, Lee, Clark, and Wallace, either alone or in combination, do not disclose, teach, or suggest the invention of Claims 30-33 and 35-37. Accordingly, reconsideration and withdrawal of the rejection are requested.

CONCLUSION

This response is being submitted on or before May 16, 2007, with a Request for Continued Examination and the required fee for the second and third month extensions of time, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment, to Deposit Account No. 04-1420.

This application now stands in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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